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App. No. 7/017,880	Filing Date 12/13/2001	Inventor(s) North, Karin	Attorney(s) SPEIGLER, ALEXANDER B.	Class 35
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Examiner
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SPEIGLER, ALEXANDER B.

Art Unit 3500	Supervisor
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DATE MAILED 1/14/02

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Please find below and or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/017,880

Applicant(s)

KURN, NURITH

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-185 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 16-31, 56-81, 97-112, 137-162, 166-167 and 172-185 is/are allowed.
- 6) ☒ Claim(s) 1-15, 32-55, 82-96, 113-136, 163-165 and 168-171 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I (claims 1-15, 32-55, 82-96, 113-136, 163-165 and 168-171) in Paper No. 10, filed on January 21, 2003 is acknowledged.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15, 32-55, 82-96, 113-136, 163-165 and 168-171 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-15, 32-55, 82-96, 113-136, 163-165 and 168-171 over "about" because it is not clear as to what is meant by "about 1 to about 10 nucleotides". Does this mean that the primer could be 0.8 or 9.8 nucleotides from the sequence of interest? Therefore, the metes and bounds of this recitation are unclear.

B) Claims 1-15 and 32-55 over "essentially the same conditions as those for primer extension" because it is not clear as to exactly what conditions constitute "essentially the same conditions as those for primer extension".

C) Claims 13-14, 44-45, 94-95, 125-126, because it is not clear these claims further limit claim 1, 32, 82, 113, respectively. Claims 1, 32, 82, 113, will already inherently amplify the target polynucleotide (i.e. since the sequence of interest is part of the target polynucleotide), and thus also inherently allow for amplification to occur simultaneously while generating multiple copies of the sequence of interest.

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### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15, 32-55, 82-96, 113-136, 163-165, 168-171 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-116 of U.S. Patent No. 6,251,639 in view of Soderlund et al. (USPN 6,013,431).

Claim 1 of the instant application recites:

1. A method of generating multiple copies of a nucleic acid sequence of interest, said method comprising the steps of:

(a) hybridizing a composite primer to a target polynucleotide, wherein the composite primer comprises an RNA portion and a 3' DNA portion, the 3' DNA portion comprising a 3' most nucleotide, such that 3' most of the 3' DNA portion hybridizes from about 1 to about 10 nucleotides from the sequence of interest.;

(b) extending the composite primer with DNA polymerase under conditions that permit primer extension, whereby a primer extension product is produced; and ;

(c) cleaving the RNA portion of the primer extension product of (b) with an enzyme that cleaves RNA from an RNA DNA hybrid such that the cleaved primer extension product dissociates from the target polynucleotide,

wherein the primer extension product is of a size that when the RNA is cleaved the cleaved primer extension product dissociates from the target polynucleotide under essentially the same conditions as those for primer extension, whereby multiple copies of the sequence of interest are produced.

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Similarly, claims 1-2 of '639 recite:

1. A method for amplifying a polynucleotide sequence complementary to a target polynucleotide sequence comprising:

(a) hybridizing a single stranded DNA template comprising the target sequence with a composite primer, said composite primer comprising an RNA portion and a 3' DNA portion;

(b) optionally hybridizing a polynucleotide comprising a termination polynucleotide sequence to a region of the template which is 5' with respect to hybridization of the composite primer to the template;

(c) extending the composite primer with DNA polymerase;

(d) cleaving the RNA portion of the annealed composite with an enzyme that cleaves RNA from an RNA DNA hybrid such that another composite primer hybridizes to the template and repeats primer extension by strand displacement,

whereby multiple copies of the complementary sequence of the target sequence are produced.

2. A method for amplifying a target polynucleotide sequence comprising:

(a) hybridizing a single stranded DNA template comprising the target sequence with a composite primer, said composite primer comprising an RNA portion and a 3' DNA portion;

(b) optionally hybridizing a polynucleotide comprising a termination polynucleotide sequence to a region of the template which is 5' with respect to hybridization of the composite primer to the template;

(c) extending the composite primer with DNA polymerase;

(d) cleaving the RNA portion of the annealed composite primer with an enzyme that cleaves RNA from an RNA DNA hybrid such that another composite primer hybridizes to the template and repeats primer extension by strand displacement to produce displaced primer extension product;

(e) hybridizing a polynucleotide comprising a promoter and a region which hybridizes to the displaced primer extension product under conditions which allow transcription to occur by RNA polymerase, such that RNA transcripts are produced comprising sequences complementary to the displaced primer extension products,

whereby multiple copies of the target sequence are produced.

Additionally, claim 23 is drawn to "characterizing a sequence of interest in a target polynucleotide, and claim 27 is drawn to "detecting a mutation in a target polynucleotide" using the amplification reaction in either claim 1 or 2.

Therefore, the claims of '639 differ from the claims of the instant application in that does not disclose the limitation that the 3' most nucleotide of the 3' DNA portion of the primer hybridizes from about 1 to about 10 nucleotides from the sequence of interest.

However, hybridizing a primer near a sequence of interest is well known in the art to aid in identifying variations. For example, Soderlund et al. teaches the hybridization of the 3' most nucleotide of the 3' DNA portion of a primer for identifying single nucleotide variations (see Figs. 1-3, cols. 3-9). Soderlund also teaches many of the common methodologies accompanying amplification and detection reactions, such as the use of probes; solid supports, and labels (cols. 3-17).

In view of the teachings of Soderlund et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of '639 so as to have included the steps of hybridizing 3' most nucleotide of the 3' DNA portion of the primer from about 1 to about 10 nucleotides from the sequence of interest, in order to have achieved the benefit of providing an effective means of detecting and identifying nucleotide variations.

### *Conclusion*

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cleuziat et al. (USPN 5,824,517)

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

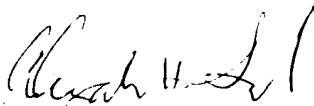
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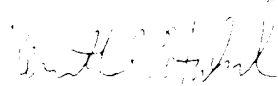
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supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
April 3, 2003

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER  
4/3/03